EXHIBIT 21

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION ***THIS DOCUMENT RELATES TO ALL CASES***	**MDL NO. 16-2738 (MAS) (RLS)**

THIRD AMENDED RULE 26 EXPERT REPORT OF DANIEL L. CLARKE-PEARSON, MD

Date: May 28, 2024

Daniel L. Clarke-Pearson, MD

I am a Professor in the Department of Obstetrics and Gynecology and the Division of Gynecologic Oncology at the University of North Carolina. I am certified by the American Board of Obstetrics and Gynecology as a specialist in obstetrics and gynecology as well as a subspecialist in gynecologic oncology.

SUMMARY OF OPINIONS

I was asked to provide my opinion in response to the following questions:

(a) Can the use of talcum powder in the genital area cause epithelial ovarian cancer (EOC)? and

(b) If so, what is the biological mechanism for this occurrence?

It is my opinion, to a reasonable degree of medical and scientific certainty, that the use of talcum powder products, including Johnson's Baby Powder and Shower to Shower, applied to the perineum of women, can cause EOC. My opinion is based on research that I have conducted in the medical and scientific literature as well as my knowledge and experience as an obstetrician-gynecologist and as a subspecialist in gynecologic oncology for over 40 years.

The increased risk associated with the genital use of talcum powder has been consistently described over decades in numerous studies. The mechanism by which talcum powder causes cancer involves: 1) ascension of particles to the fallopian tubes and ovaries; and 2) initiation of a chronic inflammatory process that includes oxidative stress and specific genetic mutations.

My opinion that genital application of talcum powder is a significant risk factor for all users and can cause epithelial ovarian cancer in some women by an accepted mechanism is strongly supported by credible scientific research. When formulating my opinions regarding causality, I considered the extensive body of literature in its totality, weighing the data and information according to its importance using the concepts outlined by Bradford Hill. The Bradford Hill factors include strength of association, consistency, specificity, temporality, biologic gradient, biologic plausibility, coherence, experiment, and analogy. These are discussed in detail later in this report.

QUALIFICATIONS

The focus of my clinical practice, teaching and research for the past 40 years has been the care of women with gynecologic cancers (cancers of the ovary, fallopian tube, uterus, cervix, vagina, and vulva). In addition, I also provide care for complex gynecologic surgical problems (endometriosis, large ovarian tumors, leiomyomata).

I received a BA from Harvard College (major in biology). I spent a year as a laboratory technician developing a device to noninvasively detect deep venous thrombosis. I then attended medical school at Case Western Reserve University School of Medicine (Cleveland, OH). After graduating in 1975, I completed a four-year residency in Obstetrics and Gynecology at Duke University Medical Center (Durham, NC). I then completed a three-year fellowship in Gynecologic Oncology at Duke. From 1982-1985, I was an assistant professor on the Duke faculty (Division of Gynecologic Oncology). From 1985-1987, I was the Director of Gynecology and Gynecologic

Oncology at the University of Illinois (Chicago, IL). I returned to Duke in 1987 to serve as the Director of Gynecologic Oncology and Director of the Gynecologic Oncology Fellowship program. I was appointed a full professor with tenure and was awarded a Distinguished Professorship (James Ingram Professor of Gynecologic Oncology) in 1993.

From 2005 until 2019, I served as Chair of the Department of Obstetrics and Gynecology at the University of North Carolina (Chapel Hill, NC). As the Robert A. Ross Distinguished Professor and Chair, I had administrative responsibilities for over 75 faculty, 28 residents in obstetrics and gynecology and 29 fellows receiving subspecialty training in eight subspecialties. Throughout my career, I provided clinical care to women with gynecologic cancers including surgery, administration of chemotherapy, and conducting clinical trials. Currently, I have a part-time position in the department and continue to educate medical students and residents in Obstetrics and Gynecology and Fellows in Gynecologic Oncology.

I have published over 250 peer-reviewed manuscripts in the medical literature. I have also written over 50 chapters for medical textbooks and edited three medical textbooks. My research has focused on the treatment of gynecologic cancers, surgical techniques, and the prevention of venous thromboembolic (VTE) disease. I have conducted the practice defining clinical trials evaluating various methods to prevent VTE in gynecologic surgery.

I have served on the editorial boards of four peer-review journals (*Obstetrics and Gynecology, Journal of Gynecologic Techniques, Journal of Gynecologic Surgery* and *Gynecologic Oncology*). I served as a board examiner for the American Board of Obstetrics and Gynecology for eighteen years. I have been actively involved with relevant medical organizations including the American College of Obstetricians and Gynecologists (ACOG), the Society of Gynecologic Oncology (SGO), the American College of Surgeons (ACS) and the Gynecologic Oncology Group (GOG). I have led numerous postgraduate continuing education courses sponsored by ACOG. Most have focused on teaching obstetricians and gynecologists complex pelvic surgery and management (and prevention) of surgical complications. I have served on several ACOG committees (Technical Bulletins, Gynecologic Management and Grievance) and was the chair of the Gynecologic Management Committee that wrote Clinical Opinions distributed to ACOG members. I also served a three-year term on the ACOG Executive Board. As a gynecologic oncologist, I have been an active member of the SGO and have served on a number of SGO Committees and the Executive Board. In 2010, I was the SGO President. As a member of the American College of Surgeons, I have presented CME lectures at the ACS annual meeting and have served on the ACS Obstetrics and Gynecology Advisory Committee and the Commission on Cancer. The GOG is a cooperative group organization sponsored by the National Cancer Institute to conduct clinical trials investigating new treatments to improve the outcomes of women with gynecologic cancers. Many of the publications on my CV (Exhibit A) derive from participation in these clinical trials.

I am a past member of the SGO Ethics Committee, past President of the Council of University Chairs of Ob Gyn (CUCOG), and currently serve as the President-Elect of the Society of Pelvic Surgeons.

My updated *curriculum vitae* is attached as **Exhibit A.**

METHODOLOGY AND MATERIALS REVIEWED

Specifically, in preparing this report, I sought to obtain relevant information through several sources. I primarily relied on a PubMed search of "talc AND Ovarian Cancer", "Ovarian Cancer AND risk factors", "Talcum Powder AND Ovarian Cancer", "Talcum Powder AND Cancer", "Talc AND Cancer", "Asbestos AND Ovarian Cancer", "Asbestos AND Cancer". These searches provided peer-reviewed papers that included original research, case-controlled studies, cohort studies, meta-analysis studies, and review papers and systematic analysis. I also searched some of the references cited in these papers. Google searches were also performed. I also reviewed a number of textbooks searching for "ovarian cancer risk factors" and "talc/talcum powder". In addition to the literature derived from these searches, I received relevant materials at my request to clarify a particular topic or answer a question. I approached this research with the same scientific rigor that I would use in my own clinical, academic, and research practice.

I assessed the data and conclusions of these peer-reviewed articles considering the strengths and weaknesses of each particular study. The medical and scientific literature on these topics varies in the quality of the study design and, at times, in conclusions. I approached each article objectively and critically, assessing for factors such as design, power, reputation of author(s), quality of journal, and potential biases. The increased risk associated with the genital use of talcum powder is consistently described over decades.

When formulating my opinions regarding causality, I considered the extensive body of literature in its totality, weighing the data and information according to its importance using the concepts outlined by Bradford Hill. Overall, I believe that the opinions expressed in this report are strongly supported by credible scientific research. The complete list of the materials I considered is attached as **Exhibit B**.

BACKGROUND AND OPINIONS

a) Overview of Ovarian Cancer

Approximately 20,000 women in the US will be diagnosed with ovarian cancer annually. To date, there is no method to screen for ovarian cancer and symptoms associated with ovarian cancer are vague and not specific. Therefore, at the time of initial diagnosis, nearly 75% of women will have ovarian cancer spread throughout the abdominal cavity, lymph nodes and into the lung (pleural effusion). Current treatment includes initial surgery to attempt to remove the bulk of the cancer ("debulking surgery") followed by treatment with multi-agent chemotherapy. Unfortunately, the majority of women will ultimately die from this malignancy.

Ovarian cancer refers to a group of malignancies found in the ovary. These groups are determined based on the ovarian cells from which they arise – germ cell, stromal, and epithelial cancers. Epithelial ovarian cancers (EOC) involve the cells on the surface of the ovary and can originate in either the ovary or fallopian tube. These account for the vast majority of ovarian cancers (greater than 90%). EOC are further subdivided based on the microscopic characteristics of the cells. These subtypes include serous, endometrioid, clear cell, mucinous, undifferentiated, or mixed. Of these, serous is by far the most common at approximately 70% of EOCs.

b) Pathogenesis of Ovarian Cancer

There are several theories as to the origin of ovarian cancer. One holds that "incessant ovulation" requires "repair" of the ovarian surface epithelium after each ovulation. The "repair" mechanism is prone to generate DNA errors (mutations) that result in malignant transformation. (Fathalla 1971). This theory is supported by observations that events that reduce ovulation are associated with a lower risk of a woman developing ovarian cancer. Pregnancy, breast feeding, and use of oral contraceptives all reduce the risk of ovarian cancer. (Havrilesky et al. 2013; La Vecchia 2017).

Before 2008, it was presumed two other cancers in women (fallopian tube and primary peritoneal) were distinct from ovarian cancer. However, Levanon recognized that many EOCs actually arise in the fallopian tube and metastasize to the ovary and peritoneal cavity. (Levanon, Crum, and Drapkin 2008). This observation is supported by molecular data (especially the frequent finding of P53 mutations in the fallopian tube and EOC metastases). (Fathalla et al. 2013; Kurman and Shih 2016; Dubeau and Drapkin 2013; Chien et al. 2015). Today, we believe that EOC, fallopian tube carcinoma and primary peritoneal carcinoma are the same entity and share similar risk factors and pathogenesis.

By definition, cancer results from gene mutations in normal cells that transform the normal cell into a cell that has lost its regulation of controlled growth. Mutations can occur through a number of processes. Some mutations may be inherited from either the patient's mother or father. BRCA1, BRCA2 and mismatch repair gene (Lynch Syndrome) mutations are such examples. In most instances, the mutations occur due to exposures such as virus (HPV virus causing cervical, anal, vulvar and oropharyngeal cancers), tobacco smoking (lung cancer) and exposure to x-rays (leukemia). Some exposures result in a chronic inflammatory response that induces mutations as the normal cell attempts to repair damage such as that caused by asbestos (pulmonary mesothelioma, ovarian cancer). These mutations can also occur spontaneously as cells (and individuals) age. (Bottazzi, Riboli, and Mantovani 2018).

c) Inflammation and Cancer

There is a clear link between inflammation (resulting in oxidative stress) and cancer risk. This is true for many types of cancers, including stomach, colon, cervix, mesothelioma, pancreas, and liver, as well as ovary. (Balkwill and Mantovani 2001; Coussens and Werb 2002; Okada 2007; Reuter et al. 2010; Crusz and Balkwill 2015; Fernandes 2015). Inflammation causes cancer through promoting cell proliferation, oxidative stress, DNA damage and gene mutations. This process is associated with many steps in the genesis of cancers including initiation, progression, metastases and chemoresistance.

Both inflammatory cells and cancers produce cytokines and chemokines that contribute to cancer growth and spread. Cytokines, particularly TNF-alpha and IL-1 beta, generate reactive oxygen species (ROS) and reactive nitrogen species (RNS). These are potent mutagens and are comparable to the cell damage caused by ionizing radiation. (Yan et al. 2006). These ROS radicals cause DNA breaks and DNA adducts. The inflammation cascade has been shown to occur in the pathogenesis of EOC. (Shan and Liu 2009; Saed, Diamond, and Fletcher 2017; Khan et al. 2011; Saed et al. 2018; Trabert et al. 2014; Savant et al. 2018; Ding et al. (2021)). Fletcher and Saed exposed normal

ovarian cells and EOC cells to talcum powder and demonstrated significant cellular effects including oxidative stress, cell proliferation, decreased apoptosis, and enzymatic activity corresponding to single nucleotide polymorphisms (SNPs) associated with inflammation and ovarian cancer. (Harper et al. 2019). Recently, Harper and Saed also demonstrated that exposure to Johnson's Baby Powder causes p53 mutations, cell proliferation and malignant transformation in normal ovarian epithelial cells. (Harper et al. 2023).

Talcum powder is known to elicit an inflammatory response in animals and humans. (Eberl and George 1948; Radic et al. 1988; NTP Toxicology and Carcinogenesis Studies of Talc (CAS No. 14807-96-6) (NonAsbestiform) in F344/N.Rats and B6C3Fl Mice (Inhalation Studies) 1993). Shukla demonstrated *in vitro* that crocidolite asbestos and non-fibrous (platy) talc caused expression of genes in ovarian epithelial cells producing inflammatory cytokines. (Shukla et al. 2009). Gates documented absence of some DNA repair mechanisms in patients who were genital talcum powder exposed when compared to controls in the New England Case Control Study. (Gates et al. 2008). In another series of *in vitro* experiments, Buz'Zard transformed normal ovarian epithelial cells to malignant cells by talc exposure. (Buz'Zard and Lau 2007). Akhtar et al. (2010, 2012) also demonstrated oxidative stress in cells exposed to talc particles. Yan and Kahn have demonstrated similar findings in their laboratories. (Yan et al. 2006; Khan et al. 2011). In 2020, Mandarino demonstrated that talc, especially in combination with estradiol, stimulated macrophages to produce increased reactive oxygen species and changes in gene expression that could promote a pro-tumorigenetic environment. (Mandarino et al. 2020). In 2021, Emi et al. conducted a follow-up study which found that the "pathway affected by talc included cell proliferation, immune responses, and signaling, immunosurveillance, apoptosis." (Emi et al. 2021). These studies provide evidence of chronic inflammation in animals and cells when exposed to talcum powder and support the findings of experiments with Johnson's Baby Powder. (Fletcher et al. 2019).

d) EOC Risk Factors

Inherited mutations such as BRCA1 and BRCA 2 are the most significant risk factors for epithelial ovarian cancer. The lifetime risk of developing ovarian cancer is 39-46% in BRCA1 carriers and 11-27% in women with BRCA 2 mutation. (Ring et al. 2017). This is compared to 1.3% lifetime risk in non-carriers. Mutations in BRCA1 and BRCA2 make up 75% of all hereditary ovarian cancers, but only account for 10-15% of all EOC. (Lancaster 2015).

Women with hereditary risk are also affected by genetic modifiers, including nongenetic and environmental factors. (Levy-Lahad 2007). Environmental factors would include exposure to talcum powder and asbestos.

Additional risk factors, both nonmodifiable and modifiable, include increasing age, family history of ovarian or breast cancer, nulliparity, early menarche or late menopause, high fat diet, infertility, endometriosis, polycystic ovarian syndrome, hormone replacement therapy, IUD use, history of pelvic inflammatory disease, obesity, and genital use of talcum powder. (Hunn and Rodriguez 2012; Mallen, Townsend, and Tworoger 2018; Park et al. 2018; Folkins et al. 2018; IOM 2016; Lheureux 2019; Phung et al. 2022). Ovarian cancer is often multifactorial; risk factors can be cumulative and synergistic. (Vitonis 2011; Wu 2018).

Multiparity, breast feeding, oral contraceptive use, tubal ligation, salpingoophorectomy, and hysterectomy (without salpingoophorectomy) reduce the risk of developing EOC. (Hunn and Rodriguez 2012; Mallen, Townsend, and Tworoger 2018; Park et al. 2018; Folkins et al. 2018).

e) Talcum Powder, Asbestos and other carcinogens

During my postgraduate (residency) training (1975-1979) in obstetrics and gynecology it was reported that talc had been identified deeply imbedded in ovarian cancer tissue samples (Henderson 1971) and raised questions about the association between talcum powder and asbestos. In subsequent studies, Henderson confirmed that these findings did not represent surface contamination. (Henderson et al. 1974; Henderson et al. 1979). It seemed plausible that asbestos (a known carcinogen) could be an EOC risk factor. However, we were taught that asbestos had been removed from talcum powder in the production process.

As a young gynecologic oncologist, it was reassuring to learn that asbestos was no longer contained in talcum powder because we knew that asbestos was a potent carcinogen. IARC monograph 100c (2012) clearly summarizes the evidence associating asbestos to mesothelioma and cancer of the lung, larynx, and ovary. Experimental models demonstrate sufficient evidence for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite) and that all forms, as well as talc containing asbestiform fibers, are carcinogenic to humans. Specifically addressing the increased risk of EOC in women exposed to asbestos in occupational settings, there are at least five cohort mortality studies (Acheson et al. 1982; Wignall and Fox 1982; Germani et al. 1999; Berry, Newhouse, and Wagner 2000; Magnani et al. 2008), two population-based cohort studies (Vasama-Neuvonen et al. 1999; Pukkala et al. 2009) and a case control study (Langseth and Kjaerheim 2004) showing a causal association between exposure to asbestos and ovarian cancer.

In the late 1970s concerns that talc could be associated with EOC were expressed by Woodruff and Longo. (Woodruff 1979). The hypothesis suggested that talc applied to the perineum (vulva) ascends to the vagina and then into the uterus and through the fallopian tubes to implant on the ovary and other peritoneal surfaces. This foreign body was known to create a potent inflammatory reaction when found in the lungs, pleural cavity and peritoneal cavity. In fact, as gynecologic surgeons, we were taught to wash the talcum powder off of our surgical gloves before opening the abdomen to prevent inflammatory reactions and adhesions.

In 1982, a case-control study was the first epidemiologic study alerting the medical community of the possible association of talc use and EOC. (Cramer et al. 1982). Cramer compared women who did and did not use talc in their perineal hygiene. Regular use of talc was found to be associated with an increased occurrence of EOC by 92% (OR of 1.92., 95% confidence interval: 1.27-2.89). Cramer wrote, “It is not clear whether this derives from the asbestos content of talc or from the uniqueness of the ovary which might make it susceptible to carcinogenesis from both talc and other particulates.”

Talcum powder also contains other carcinogens including asbestos, talc containing asbestiform fibers (fibrous talc), heavy metals such as nickel, chromium and cobalt (possible 2b), and other

inflammatory agents, toxins, and carcinogens contained in the fragrance chemicals in talcum powder. (Expert Report of Longo and Rigler 2019; Exhibit 28, Deposition of John Hopkins, Ph.D., MDL No. 2378, 2018; Exhibit 47, Deposition of Julie Pier, MDL No. 2738, 2018; Expert Report of Michael Crowley, Ph.D., MDL No. 2738, 2018). In the analysis of historical samples of J&J talcum powder products performed by Drs. Longo and Rigler, asbestos was present in the majority of samples with fibrous talc (talc fibers) seen in virtually all bottles tested. (Longo and Rigler report). In October 2019, FDA found asbestos in a sample of Johnson's Baby Powder purchased online, resulting in Johnson & Johnson recalling one lot of the product – 33,000 bottles. (BMJ 2019).

Fibrous talc (synonymous with talc in an asbestiform habit, asbestiform talc, or talc fibers) and all forms of asbestos are recognized by IARC as carcinogenic to humans, including ovarian cancer. (IARC 2012). According to IARC, consumer products are the primary sources of talc for the general population (non-occupational). Inhalation and perineal application and migration of talcum powders are the primary routes of exposure. (IARC 2012). The carcinogenicity of asbestos and other mineral fibers involves inflammation, oxidative stress, DNA damage and mutation, inducement of cell proliferation and transformation, and resistance to apoptosis. (IARC 2012, Moller 2013, Mossman 2018, Egilman 2019).

f) Epidemiology Studies

The association of talcum powder and EOC is based on several types of epidemiologic studies. Of course, a randomized controlled double-blinded trial would be more conclusive. However, a randomized trial would be unethical given the evidence that talcum powder causes EOC.

When looking at these epidemiologic studies in their totality, the data shows a consistent, statistically significant increased risk of developing EOC with perineal talcum powder use. Overall, the risk is increased 20-60% when compared with women who did not use talcum powder.

The original case control study published by Cramer et al. in 1982 evaluated the use of perineal talcum powder in 215 white women with EOC (29 cases were "borderline" or ovarian cancer of low malignant potential). These women with EOC were matched by race, age and residence to 215 women in the same community. Talc exposure from surgical gloves, diaphragm use, and perineal use was ascertained. Talc was used by 42.8% of women with EOC and only 28.4% of women who did not have EOC. Any perineal talc exposure showed a statistically significant relative risk of 1.92 (95% confidence limits 1.27-2.89), equivalent to a 92% increased chance of developing EOC. (Cramer et al. 1982).

Subsequently, there have been at least 24 other case-control studies looking at the association of talc and EOC. Overall, the case-control studies show a 30-40% increased risk of EOC associated with genital talcum powder use. These individual studies vary in size and quality, and I weighted them accordingly. Three recent case-control studies replicated previous studies showing an increased risk of EOC in women using perineal talcum powder. Wu evaluated 1701 Californian women with EOC and found talc significantly increased the risk of EOC by 40% in whites, 20% in Hispanics and 56% in African Americans. (Wu et al. 2015). Owing to the small number of

African American women in this study, the findings were not statistically significant.

Subsequently, the National Cancer Institute sponsored a multi-center study of African American women and found a 44% increase in EOC associated with talc use. A dose-response was also found for duration of use and number of lifetime applications ($p<.05$). (Schildkraut et al. 2016). Cramer performed a case control study (with additional pooled data) in 2016 that included nearly 4,000 women with EOC finding an elevated EOC risk of 33% (OR 1.33, 95% CI 1.16, 1.52). Risk increased with frequency and duration of use. (Cramer et al. 2016).

I also reviewed four cohort studies (Gertig, Gates, Houghton, Gonzalez). While not addressing talcum powder usage as the primary research question, these studies also reported the relationship between powder usage and ovarian cancer. The Gertig study showed a statistically significant increased risk of serous epithelial ovarian cancer with talcum powder users. However, I found these studies to have significant limitations due to defective trial design and reporting of their data.

Recently, O'Brien et al. published a pooled study of the data from four cohort studies. The authors concluded that there was not a statistically significant association between the genital use of powder and an increased risk of ovarian cancer. (O'Brien et al. 2020). However, closer examination of the data indicates a significant increased risk in women with an intact reproductive tract. Additional criticisms of the paper are outlined in Letters to the Editor (from Drs. Cramer, Harlow, Murray, and Rothman) and include the possibility of the study being underpowered, the discordance between the findings and conclusions of the authors, the lack of consistency among the cohort inquiries, and the failure to take into account the age and menopausal status of the subjects. (O'Brien et al. 2020; Gossett 2020; Letters to Editor JAMA 2020).

While case-control studies and cohort studies are compelling, in my opinion, meta-analysis studies are much stronger in that they include larger numbers of patients resulting in greater statistical power. I reviewed eight meta-analyses, one pooled study (Terry) and one cohort-only pooled study (O'Brien) reported between 1995 and 2022. All of these studies, with the exception of O'Brien, report a statistically significant increased risk of EOC in women who use talcum powder in the genital area.

Penninkilampi reported that there was a further increase in EOC in women who used talcum powder more frequently. In those who had greater than 3,600 lifetime applications the odds ratio increased to 1.42 (OR 1.42; 95% CI 1.25-1.61) when compared with women who used < 3,600 applications (OR 1.32; 95% CI 1.15-1.50). In this study, talcum powder use was associated with an increased incidence of endometrioid and serous EOC but not mucinous or clear cell types. (Penninkilampi and Eslick 2018). These results were similar to the meta-analysis conducted by Berge et al. (2018), summary relative risk 1.22 (95% CI: 1.13–1.30).

The Taher meta-analysis was commissioned by Health Canada and formed the epidemiological basis for its assessment of the risks of cosmetic talc (non-asbestos containing). Health Canada performed an extensive review of the subject that included a Bradford-Hill analysis and concluded: "With regards to perineal exposure, **analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer**. The available data are indicative of a

causal effect. Given that there is potential for perineal exposure to talc from the use of certain self-care products (e.g., body powder, baby powder, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs, bubble bath), a potential concern for human health has been identified." (Health Canada Assessment 2021).

In a recent meta-analysis by Davis, et al. (2021), data from five studies in the Ovarian Cancer in Women of African Ancestry Consortium were considered. Participants included 620 African-American ovarian cancer cases and 2,800 white cases, and 1,146 African-American controls and 6,735 white controls who answered questions on genital powder use prior to 2014. For all cases with frequency of use > once per week, there was an increased risk of 1.31 (95% CI 1.15-1.48), with an odds ratio of 1.31 (95% CI 1.13-1.52) for high-grade serous and 1.29 (95% CI 1.09-1.54) for all other histotypes. The authors concluded that "the associations between genital powder use and ovarian cancer risk were similar across race and did not materially vary by histotype."

In a study performed by the Ovarian Cancer Association Consortium, the data of 9 case-controlled studies were pooled to consider the effect of well-established ovarian cancer risk factors in women with endometriosis and without endometriosis. The pooled analysis included 8500 women with ovarian cancer and 13,592 controls. For women with endometriosis, an inflammatory process, the increased risk of ovarian cancer with genital talc use was 38% (OR 1.38, 95% CI 1.04-1.84); for women without endometriosis, the increased risk was 12% (OR 1.12, 95% CI 1.01-1.25). (Phung et al. 2022).

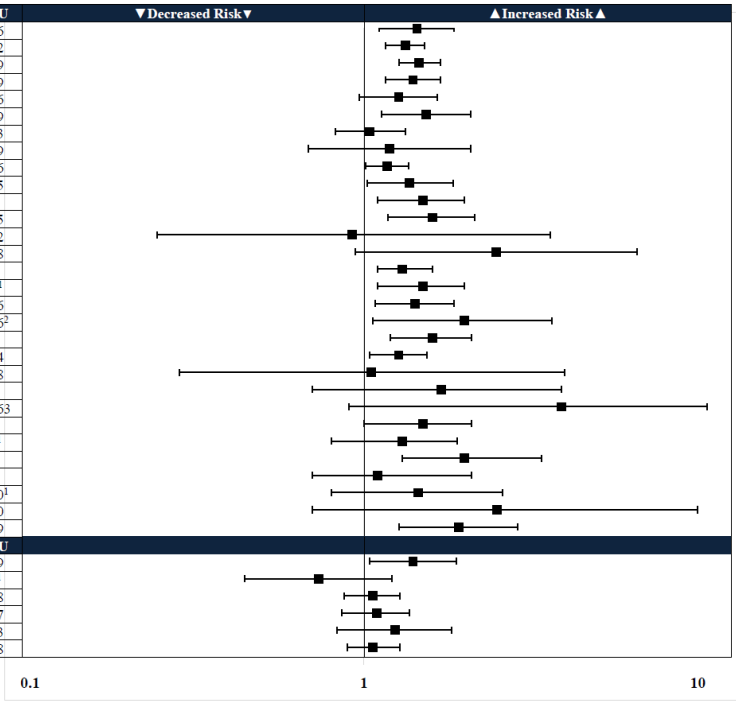
Woolen, et al. (2022) conducted a systematic review and meta-analysis of eleven studies, focusing on frequent use of genital talc which was defined as ≥ 2 times per week. "Frequent talcum powder use was associated with an elevated risk of ovarian cancer (adjusted pooled summary odds ratio 1.47 (95% CI 1.31, 1.65, P<0.0001)."

With new data from the Sister Study, O'Brien, et al. (2024) published a study showing "in models adjusted for exposure misclassification, genital talc use was positively associated with ovarian cancer (HR range, 1.17-3.34)." Women who used talc frequently had an increased risk of 1.81 (1.29 to 2.53), and women who used genital talc long-term (≥2 decades) had an increased risk of 2.01 (1.39 to 2.91). Genital use of talcum powder by women during their 20s resulted in an increased risk of 1.88 (1.37 to 2.57) and for those women who used in their 30s, 2.08 (1.50 to 2.89). For these data points, the study found an increased risk of ovarian cancer with and without correction for recall bias.

In summary, when evaluating all epidemiological studies, there is a consistent and statistically significant increased risk of developing EOC with perineal talcum powder use. Data from the case control, cohort, meta-analysis, and pooled studies are shown in the following forest plots prepared at the direction of Dr. Anne McTiernan:

Figure 2: Case-Control and Cohort Studies

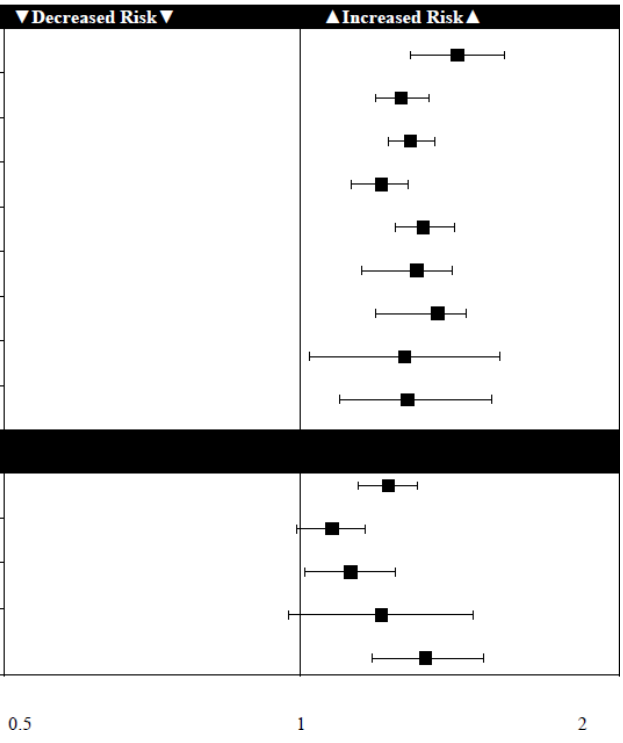
Case-Control Studies	Natl	Cases	Controls	Pop	DR	RR	CI L	CI U
Schildkraut (2016)	US	584	745	Pop.	Yes	1.44	1.11	1.86
Cramer (2016)	US	2041	2100	Pop.	Yes	1.33	1.16	1.52
Wu (2015)	US	1791	2391	Pop.	Yes	1.46	1.27	1.69
Kurta (2012)	US	902	1802	Pop.	N/A	1.4	1.16	1.69
Rosenblatt (2011)	US	812	1313	Pop.	No	1.27	0.97	1.66
Wu (2009)	US	609	688	Pop.	Yes	1.53	1.13	2.09
Moorman (2009) - Wh	US	1114	1086	Pop.	N/A	1.04	0.82	1.33
Moorman (2009) - AA	US	1114	1086	Pop.	N/A	1.19	0.68	2.09
Merritt (2008)	Aus	1576	1509	Pop.	Yes	1.17	1.01	1.36
Mills (2004)	US	256	1122	Pop.	No	1.37	1.02	1.85
Ness (2000)	US	767	1367	Pop.	Incpl	1.5	1.1	2.0
Cramer (1999)	US	563	523	Pop.	Yes	1.6	1.18	2.15
Wong (1999)	US	499	755	Hosp.	Incpl	0.92	0.24	3.62
Godard (1998)	Can	170	170	Pop.	N/A	2.49	0.94	6.58
Green (1997)	Aus	824	855	Pop.	Incpl	1.3	1.1	1.6
Cook (1997)	US	313	422	Pop.	No	1.5	1.1	2.0[1]
Chang (1997)	Can	450	564	Pop.	No	1.42	1.08	1.86
Shushan (1996)	Isr	200	408	Pop.	N/A	2	1.06[2]	3.66[2]
Cramer (1995)	US	450	454	Pop.	N/A	1.6	1.2	2.1
Purdie (1995)	Aus	824	860	Pop.	N/A	1.27	1.04	1.54
Tzonou (1993)	Gre	189	200	Hosp.	N/A	1.05	0.28	3.98
Rosenblatt (1992)	US	77	46	Hosp.	Yes	1.7	0.7	3.9
Chen (1992)	Chn	112	224	Pop.	N/A	3.9	0.9	10.63
Harlow (1992)	US	235	239	Pop.	Yes	1.5	1.0	2.1
Booth (1989) – daily	UK	235	451	Hosp.	Yes	1.3	0.8	1.9[1]
Booth (1989) – wkly	UK	235	451	Hosp.	Yes	2.0	1.3	3.4
Harlow (1989)	US	116	158	Pop.	N/A	1.1	0.7	2.1
Whittemore (1988)	US	188	539	H&P	Yes	1.45	0.81[1]	2.60[1]
Hartge (1983)	US	135	171	Hosp.	N/A	2.5	0.7	10.0
Cramer (1982)	US	215	215	Pop.	N/A	1.92	1.27	2.89
Cohort Studies	**Natl**	**Cases**	**Non**	**Flw Up**	**DR**	**RR**	**CI L**	**CI U**
O'Brien (2024)	US	292	40,536	13	Yes	1.4	1.04	1.89
Gonzalez (2016)	US	154	41,500	6.6	N/A	0.73	0.44	1.2[1]
Houghton (2014)	US	429	61,147	12.4	Incpl	1.06	0.87	1.28
Gertig (2000)	US	307	78,323	N/A	Incpl	1.09	0.86	1.37
Gates (2008)	US	210	600	N/A	Yes	1.24	0.83	1.83
Gates (2010)	US	797	78,323?	N/A	N/A	1.06	0.89	1.28



[1] Corrected data-point from study text (report figure: Cook 1997 CI Upper 2.3; Gonzalez CI Upper 1.21; Booth 1989 CI Upper 1.0; Whittemore CI p=0.06).
[2] Corrected data-point from defense expert report(s) (report figure: p=0.04).

Meta-Analyses and Pooled Studies (All Ovarian)

Meta-Analyses	Studies	Cases	DR	RR	CI L	CI U
Woolen (2022)	11	6542	Yes	1.47	1.31	1.65
Taher (2018)	27	17,149	Yes	1.28	1.2	1.37
Penninkilampi (2018)	27	14,311	Yes	1.31	1.24	1.39
Berge (2018)	27	N/A[1]	Yes	1.22	1.13	1.3
Langseth (2008)	20	N/A[1]	N/A	1.35	1.26	1.46
Huncharek (2003)	16	5260	No[2]	1.33	1.16	1.45
Cramer (1999)	14	3834	N/A	1.4	1.2	1.5
Gross (1995)	10[3]	1509	N/A	1.29	1.02	1.63
Harlow (1992)	6	1106	N/A	1.3	1.1	1.6
Pooled Meta-Analyses	**Studies**	**Cases**	**DR**	**RR**	**CI L**	**CI U**
Terry (2013)	8	8,525	Yes	1.24	1.15	1.33
O'Brien (2020)	4	2168	No	1.08	0.99	1.17
↳ Patent Reproductive Tract	4	1384	Yes	1.13	1.01	1.26
Davis (2021)	5	AA:620 Wh:2800	No	1.22 1.36	0.97 1.19	1.53 1.57



g) Migration and transport of talc particles to the ovaries and other pelvic organs

How is it possible for cosmetic talcum powder, applied to the perineum, to reach the fallopian tube and ovary and cause an inflammatory response that could result in malignant transformation?

As compared to males, the female reproductive tract is open and allows migration of potential pathogens into the peritoneal cavity. The female reproductive tract is in continuity between the peritoneal cavity and the external environment. For example, an ovum extruded from the ovary (an intraperitoneal organ) can progress down the fallopian tube to the uterine cavity, implant and result in a pregnancy that delivers vaginally. The converse is also obvious. It is clearly recognized that sperm (including sperm and sperm particles which would be non-motile) ascend from the vagina through the uterus and into the fallopian tube and into the peritoneal cavity. (Jones and Lopez 2006). Sexually transmitted bacterial infections (for example, gonorrhea and chlamydia) ascend from the vagina to the tube and ovary resulting in pelvic inflammatory disease and tubo-ovarian abscesses. While sperm and bacteria are "motile", non-motile substances have been demonstrated to ascend from the vagina to the peritoneal cavity. As far back as 1961, Egli demonstrated that carbon particles placed in the posterior vaginal fornix were observed in the fallopian tubes within less than one hour in two of three patients tested. (Egli and Newton 1961). Venter and Iturralde placed albumin microspheres labelled with 99mTc into the vagina. (Venter and Iturralde 1979). During pelvic surgery the following day, radioactive levels were found in the tubes and ovaries in nine of 14 cases. Sjösten conducted a trial that showed that powder on gloves used to perform a gynecologic exam resulted in powder detected in the peritoneal fluid, tubes and ovaries one day after the examination. (Sjösten, Ellis, and Edelstam 2004). Likewise, talc has been detected on the ovaries following surgical oophorectomy. (Henderson et al. 1971; Heller, Gordon, et al. 1996; Heller, Westhoff, et al. 1996). In a recent study using correlative light and scanning electron microscopy, morphologically demonstrated talc particles were found in multiple pelvic organ sites, including pelvic tissues and lymph nodes simultaneously. (McDonald 2019). Talc particles and fibers found in pelvic tissues have been shown to be similar to those found in cosmetic talcum powder products, further supporting migration and transport to pelvic organs. (Johnson 2020).

I reviewed the small body of literature suggesting that migration of particles does not occur and do not think these studies are compelling.

I believe that ascension of talcum powder and its constituents through the genital tract is the most important route of exposure. However, inhalation is another plausible mechanism. (IARC 2012; Steiling et al. 2018, Steffen et al. 2020; Health Canada 2021). With either route, at least some of the talcum powder components are likely to be absorbed into the lymphatic system and bloodstream, representing another mechanism for exposure to internal organs.

CAUSATION ANALYSIS

In my opinion, genital application of talcum powder is a significant risk factor for all users and can cause epithelial ovarian cancer in some women by an accepted mechanism. As an academic and practicing physician, I made this determination in the context of Bradford Hill considerations as follow:

Strength and consistency: This opinion is supported by overwhelming epidemiologic evidence showing that the genital use of talcum powder statistically increases a woman's risk of developing EOC by approximately 30 percent (OR 1.31 Penninkilampi 2018; OR 1.28 Taher et al. 2019; OR 1.31 Davis et al. 2021). For frequent users of talcum powder, the risk is higher (e.g., Woolen et al. 2022; O'Brien et al. 2024). All previous meta-analyses reported similar increases in the risk of developing EOC with the use of talcum powder. In my view, especially when considering the severity and frequency of ovarian cancer and the preventable nature of talcum powder usage, this finding is critically important and consistently supported by numerous studies.

Specificity: Based on the epidemiologic studies cited in this report, there appears to be a specific ovarian cancer caused by talcum powder: epithelial ovarian cancer (EOC). Other reproductive cancers do not appear to have an association. This association satisfies this consideration, although I did not weigh this factor to be as important as strength and consistency.

Temporality: In many cancers where there are identified etiologic agents (smoking and lung cancer, HPV infection and cervical cancer) there is a latency period (time from exposure to the onset of the cancer) that can extend over decades. (Nadler and Zurbenko 2014). This concept applies to the latency period of talcum powder use before a woman develops ovarian cancer, thus fulfilling this consideration.

Biologic Gradient/Dose-response: Measuring the "dose" of talcum powder used by an individual woman is difficult to ascertain and has been dependent on recall by the woman. In general, studies have attempted to capture the application "frequency" (daily? Only used on perineal pads during menstrual cycle?) or duration of use (how many years?). In addition, biologic gradient or dose-response is not always linear (e.g., asbestos exposure and mesothelioma is generally thought to have a "threshold response"). A number of studies have demonstrated an association between "dose" and the occurrence of EOC (response). (Terry et al. 2013; Schildkraut et al. 2016; Daniel W. Cramer et al. 2016; Penninkilampi and Eslick 2018; Woolen et al. 2022). More recently, *in vitro* studies have demonstrated a dose dependent effect of talcum powder on molecular changes associated with carcinogenesis. (Fletcher et al. 2019; Mandarino et al. 2020).

Plausibility: This is obviously a critical factor when forming opinions on causation of a risk factor. Evidence shows that talcum powder ascends from the perineum through the vagina, cervix and uterus into the fallopian tubes and onto the ovary. Talcum powder is known to be an agent that causes inflammation. An inflammatory reaction caused by talcum powder on the tube and surface of the ovary results in genetic mutations and carcinogenesis. Talcum powder causes ovarian cancer through this mechanism. The "talcum powder agent" includes numerous constituents such as platy talc, asbestos, fibrous talc, heavy metals and/or chemicals contained in fragrances added to talcum powder, all of which cause an inflammatory reaction leading to carcinogenesis.

Coherence: Epidemiological data, *in vitro* and *in vivo* research are consistent in explaining the pathogenesis of EOC through the inflammatory mechanisms described above. (Saed, Diamond, and Fletcher 2017; Savant et al. 2018; Ding et al. 2021). Further, this is consistent with the causes of other cancers.

Experiment: There are no randomized trials comparing outcomes of women who use or who do not use talcum powder in their perineal hygiene. Further, such a trial at this point in time would be unethical. How could we expose women to talcum powder when the existing evidence supports causation of EOC? Laboratory research (*in vitro*) present evidence to support the biologic, genetic, epigenetic and neoplastic consequence to ovarian epithelium when exposed to talcum powder. (Buz'Zard and Lau 2007; Shukla et al. 2009; Akhtar et al. 2010; Akhtar et al. 2012; Fletcher et al. 2019; Mandarino et al. 2019; Emi et al. 2021; Harper et al. 2023).

Analogy: There are numerous reports in the medical literature of minerals similar to talc causing cancer. Probably the most significant example is asbestos and lung cancer (mesothelioma).

CONCLUSION

It is my opinion, based on research that I have conducted in the medical and scientific literature as well as my knowledge and experience as an obstetrician-gynecologist and as a subspecialist in gynecologic oncology for over 40 years, that the use of talcum powder products including Johnson's Baby Powder and Shower to Shower, applied to the genital area of women, can cause EOC. The mechanism by which talcum powder causes cancer involves: 1) ascension of particles to the fallopian tubes and ovaries and 2) initiation of an inflammatory process that includes oxidative stress and specific genetic mutations. The additional studies that have been published and I have considered since my prior report reaffirm my opinion that the genital use of talcum powder can cause ovarian cancer.

These opinions are made to a reasonable degree of medical and scientific certainty.

I reserve the right to supplement or amend this report if new information becomes available. I reserve the right to review and remark on the reports and testimony of Defendants' experts. My prior testimony is attached as **Exhibit C**.

Exhibit A

Updated: March 2023

UNC SCHOOL OF MEDICINE
CURRICULUM VITAE

Personal Information

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Education and Training

Fellow	Duke University Medical Center	1979-1981	Gynecology Oncology
Residency	Duke University Medical Center	1975-1979	Obstetrics and Gynecology
Medical Degree	Case Western Reserve University School of Medicine	1971-1975	Medicine
Bachelor of Arts	Harvard College	1966-1970	Biology

Professional Experience

Professor	University if North Carolina, Chapel Hill	July 2019-present	Obstetrics and Gynecology Division of Gynecologic Oncology
Active Consulting Staff	The Outer Banks Hospital	Oct 2009 – 2012	Medicine/Oncology Section
Chairman	University of North Carolina at Chapel Hill School of Medicine	September 2005 – July 2019	Obstetrics and Gynecology
Robert A. Ross Distinguished Professor	University of North Carolina at Chapel Hill School of Medicine	September 2005 – July 2019	Obstetrics and Gynecology

James M. Ingram Professor of Gynecologic Oncology	Duke University Medical Center	July 1993-2005	Gynecologic Oncology
Division Director	Duke University Medical Center	July 1987-2005	Gynecologic Oncology
Professor	Duke University Medical Center	July 1987-2005	Obstetrics and Gynecology
Director of Gynecology and Gynecologic Oncology	University of Illinois at Chicago	January 1985-1987	Obstetrics and Gynecology
Associate Professor	University of Illinois at Chicago	July1984-1987	Obstetrics and Gynecology
Associate Professor	Duke University Medical Center	January1984	Obstetrics and Gynecology
Co-Director, Trophoblastic Disease Center	Duke University Medical Center	July 1982-1984	Obstetrics and Gynecology
Assistant Professor	Duke University Medical Center	July1980-1984	Obstetrics and Gynecology

Honors and Awards

2022	President-elect, Society of Pelvic Surgeons
2022	Distinguished Service Award, North Carolina Obstetrics and Gynecology Society
2019	UNC Lifetime Achievement Award for Medical Student Education
2009-2010	President, Society of Gynecologic Oncologists
2001-2020	America's Top Doctors for Women (176 Physicians): Women's Health
2008	CREOG National Faculty Award for Excellence in Resident Education
2004	Invited Panel Member, International Consensus Conference of the Prevention of Venous Thromboembolism, Windsor, England
2002	ACOG Roy Pitkin/Elsevier Award: One of top four papers published annually in Obstetrics and Gynecology
2001-present	America's Top Doctors for Women: Women's Health

1991	Invited Panel Participant, Consensus Meeting on the Prevention of Thromboembolism - Windsor, England
1985	Clinical Research Prize Paper – ACOG District Meeting
1981-1984	Junior Faculty Clinical Fellowship – American Cancer Society
1982	Donald F. Richardson Memorial Prize Paper -Best research paper presented by a Junior Fellow at a District ACOG Meeting
1981	Clinical Research Paper, Second Place ACOG Annual Clinical Meeting
1981	Junior Fellow First Prize Paper – ACOG District IV
1980	American Cancer Society Clinical Fellow
1979	Junior Fellow First Prize Paper – ACOG District IV

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Original Research

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1. Performance enhancing anabolic steroid abuse in women. Committee Opinion No. 484. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;117:1016–18.

2. Understanding and using the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. Committee Opinion No. 505. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;118:754–60.

3. Expedited partner therapy in the management of gonorrhea and chlamydia by obstetrician–gynecologists. Committee Opinion No. 506. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;118:761–6.

4. Management of vulvar intraepithelial neoplasia. Committee Opinion No. 509. American College of Obstetricians and Gynecologists. ObstetGynecol 2011;118:1192–4.

5. Vaginal placement of synthetic mesh for pelvic organ prolapse. Committee Opinion No. 513. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;118:1459–64.

6. Compounded bioidentical menopausal hormone therapy. Committee Opinion No. 532. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;120:411–5.

7. Well-woman visit. Committee Opinion No. 534. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;120:421–4.

8. Reprocessed single-use devices. Committee Opinion No. 537. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012:120:974–6.

9. Risk of venous thromboembolism among users of drospirenone-containing oral contraceptive pills. Committee Opinion No. 540. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;120:1239–42.

10. Over-the-counter access to oral contraceptives. Committee Opinion No. 544. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012:120;1527-31.

11. Postmenopausal estrogen therapy: route of administration and risk of venous thromboembolism. Committee Opinion No. 556. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:887–90.

12. Management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. Committee Opinion No. 557. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:891–6.

13. Integrating immunizations into practice. Committee Opinion No. 558. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:897–903.

Developed during tenure as Committee Chair:

1. Female age-related fertility decline. Committee Opinion No. 589. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:719–21.

2. Hormone therapy and heart disease. Committee Opinion No. 565. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1407–10.

3. Professional liability and gynecology-only practice. Committee Opinion No. 567. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:186.

4. Solutions for surgical preparation of the vagina. Committee Opinion No. 571. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:718–20.

5. Understanding and using the U.S. Selected Practice Recommendations for Contraceptive Use, 2013. Committee Opinion No. 577. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:1132–3.

6. Von Willebrand disease in women. Committee Opinion No. 580. American College of Obstetricians and Gynecologists. Obstet Gyne-col 2013;122:1368–73.

7. Addressing health risks of noncoital sexual activity. Committee Opinion No. 582. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:1378–83.

Editorials and Letters

1. **Clarke-Pearson DL**, Geller EJ. Complications of Hysterectomy. Obstet Gynecol 2013; 121:1-21.

2. **Clarke-Pearson DL**. Thromboprophylaxis in Gynecologic Surgery: Why are we Stuck in 1975? Obstet Gynecol 2011; 118: 973.

3. Martino M, Rajaram L, Maxwell GL, **Clarke-Pearson DL**. Combination Prophylaxis for Thromboembolism Prevention among Gynecologic Oncology Patients Perioperatively. (Letter) Gynecol Oncol 2008; 109: 426-27.

4. **Clarke-Pearson DL**: Prevention of venous thrombosis following gynecologic Surgery. J Gynecol Tech 1(1):11-17, 1995.

5. **Clarke-Pearson DL**: Crafting the operative note: techniques critical to success (editorial). J Gynecol Tech 1(3):119-120, 1995.

6. **Clarke-Pearson, DL**: Reassessment of ovarian cancer: What are our goals? Gynecol Oncol 52:151-153, 1994.

7. Soper JT, **Clarke-Pearson DL**, Berchuck A: The clinical significance of blood transfusion at the time of radical hysterectomy. (Letter). Obstet Gynecol 77:165, 1991.

8. **Clarke-Pearson DL**: The importance of calf vein thrombosis. N Eng J Med 302:752, 1980.

Published Abstracts

1. Barber EL, **Clarke-Pearson DL**. Risk of venous thromboembolism in minimally invasive versus open hysterectomy for endometrial cancer. SGO Annual Meeting 2016.

2. Barber EL, Gehrig PA, **Clarke-Pearson DL**. A risk assessment score for postoperativeVTE among patients undergoing minimally invasive surgery for gynecologic cancer. SGO Annual Meeting 2016.

3. Barber EL, **Clarke-Pearson DL**. Validity of currently available venous thromboembolism risk scores among gynecologic oncology patients.

4. Look K, Brunetto VL, **Clarke-Pearson DL**, Averette H, Major FJ, Alvarez RD, Homesley HD, Zaino R: An analysis of cell type in patients with surgically stages stage IB carcinoma of the cervix: A Gynecologic Oncology Group (GOG) Study. Abstract. Gynecol Oncol 60:117, 1996.

5. Omura GA, Blessing J, Vaccarello L, Berman M, Mutch D, **Clarke-Pearson DL**, Anderson B: A randomized trial of Cisplatin versus Cisplatin + Mitolactol versus Cisplatin + Ifosfamide in advanced squamous carcinoma of the cervix by the Gynecologic Oncology Group (GOG). Abstract. Gynecol Oncol 60:120, 1996.

6. Omura GA, Blessing J, Vaccarello L, Berman M, Mutch D, **Clarke-Pearson DL**, Anderson B: A randomized trial of Cisplatin versus Cisplatin + Mitolactol versus Cisplatin + Ifosfamide in advanced squamous carcinoma of the cervix by the Gynecologic Oncology Group (GOG). Abstract. ASCO, 1995.

7. Alberts DS, Liu PY, Hannigan EV, O'Toole R, Williams SD, Vogel S, Franklin FW, **Clarke-Pearson** DL, Malviya VK, Dubeshter B, Hoskins W, Adelson M, Alvarez RD, O=Sullivan J, Garcia DJ, Sparks D, Rothenberg ML: Phase III study of intraperitoneal (IP) Cisplatin CDDP)/Intravenous (IV) Cyclophosphamide (CPA) vs. IV CDDP/IV CPA in patients (Pts) with optimal disease stage III ovarian cancer: A SWOG-GOG Intergroup Study. Abstract. ASCO, 1995.

8. Stehman FB, Bundy BN, Ball H, **Clarke-Pearson DL**: Sites of failure and times to failure in carcinoma of the vulva treated conservatively: A Gynecologic Oncology Group Study. Abstract. AGOS 1995.

9. Omura GA, Blessing J, Vaccarello L, Berman M, Mutch D, **Clarke-Pearson D**, Anderson B: A randomized trial of cisplatin versus cisplatin + mitolactol (CM) versus cisplatin + ifosfamide (CIFX) in advanced squamous carcinoma of the cervix (SCC) by the Gynecologic Oncology Group (GOG). Presented at the 1995 American Society of Clinical Oncology Annual Meeting.

10. **Clarke-Pearson DL**, Berchuck A, Kohler M, Rodriguez GC: Retroperitoneal drains/morbidity of nodes. Society of Gynecologic Oncologists, 1993.

11. Hoskins WJ, McGuire WP, Brady MS, Copeland L, Homesley HD, **Clarke-Pearson DL**: Serum CA-125 for prediction of progression in advanced epithelial ovarian carcinoma (AOC). The Gynecologic Oncology Group (GOG). Proc ASOC (Abstract #707) 11:223, March 1992.

12. McGuire WP, Hoskins WJ, Brady MF, Homesley HD, **Clarke-Pearson DL**: A Phase III trial of dose intensive (DI) cisplatin (CDDP) and Cytoxan (CTX) in advanced ovarian cancer (AOC). Proc ASCO, March 1992.

13. Hoskins WJ, McGuire WP, Brady MS, Homesley HD, **Clarke-Pearson DL**: Serum CA-125 for prediction in advanced epithelial ovarian cancer (AOC). The Gynecologic Oncology Group (GOG).

Third Meeting of the International Gynecologic Cancer Society, September 22-26, 1991, Cairns, Australia.

14. McGuire WP, Hoskins WJ, Brady MS, Homesley HD, **Clarke-Pearson DL**: A Phase II trial of dose intense (DI) versus standard dose (SD) Cisplatin (CDDP) and Cytoxan (CTX) in advanced ovarian cancer (AOC). The Gynecologic Oncology Group (GOG). Third Meeting of the International Gynecologic Cancer Society, September 22-26, 1991, Cairns, Australia.

15. Shpall E, **Clarke-Pearson DL**, Soper JT, Berchuck A, Jones R, Bast R, Lider Y, Vanacek K, Tyler T, Peters W: High dose alkylating agent chemotherapy with autologous bone marrow support in patients with Stage III/IV epithelial ovarian cancer. Society of Gynecologic Oncologists, 1990.

16. Soisson AP, Soper JT, Berchuck A, Creasman WT, **Clarke-Pearson DL**: The role of radiation therapy following radical hysterectomy for carcinoma of the cervix. Society of Gynecologic Oncologists, 1989.

17. Berchuck A, Soisson AP, Soper JT, **Clarke-Pearson DL**, McCarty KS Jr, Bast RC Jr:Cellular expression of CA-125 and metastatic potential of endometrial adenocarcinoma. Society of Gynecologic Oncologists, 1989.

18. Soisson AP, Berchuck A, Soper JT, **Clarke-Pearson DL**, Flowers J, Kinney R, McCarty KSJR, Bast RC Jr: TAG-72 expression in benign and malignant endometrium. American College of Obstetricians and Gynecologists, Armed Forces District Meeting, 1988.

19. Christensen C, McCarty KS Jr, Flowers J, Soper JT, McCarty KS Sr, **Clarke-Pearson DL**: Progesterone receptor in ovarian carcinoma: Comparison of biochemical and immunohistochemical techniques. American College of Obstetricians and Gynecologists, Annual Clinical Meeting, 1988.

20. Genkins SM, Sotsman HD, Spritzer CE, Herfkens RJ, Carroll BA, Kadir S, **Clarke-Pearson DL**, Coleman RE: Diagnosis of deep venous thrombosis: Comparison of venography with four noninvasive techniques. The Radiological Society of North America, 1988.

21. Mutch DG, Soper JT, Babcock CJ, Christensen CW, **Clarke-Pearson DL**, Hammond CB: Recurrent gestational neoplasia: Experience of the Southeastern Trophoblastic Disease Center. Abstract, Gynecol Oncol 29:133, 1988.

22. Christensen C, McCarty KS Jr, Flowers J, Soper JT, McCarty KS Sr, **Clarke-Pearson DL**: Analysis of estrogen receptor in ovarian carcinoma using biochemical and monoclonal antibody assays. Presented at American College of Obstetricians and Gynecologists District IV Meeting. Atlanta, Georgia, October 1987.

23. **Clarke-Pearson DL**, Creasman WT: Prevention of postoperative deep venous thrombosis by two intense low-dose heparin regimens: A controlled trial. Abstract, Society of Pelvic Surgeons, 1986.

24. **Clarke-Pearson DL**, DeLong ER, Synan IS, Coleman RE, Creasman WT: Variablesassociated with postoperative deep venous thrombosis. Abstract, Society of Gynecologic Investigation, p. 119, 1986.

25. Siegel RS, Kessler CM, **Clarke-Pearson DL**, Barth S, Fortune W, Reba R, Coleman RE: Application of Indium-111-labeled donor platelets to detection of deep venous thrombosis. Clin Res 32:323A, 1984.

26. Creasman WT, Henderson D, **Clarke-Pearson DL**: Use of estrogens after treatmentfor adenocarcinoma of the endometrium. Gynecol Oncol 17:2, p. 255, 1984.

27. Siegel RS, **Clarke-Pearson DL**, Barth S, Fortune W, Lewis RJ, Reba R, Coleman RE: Application of Indium-111-labeled donor platelets to detection of deep venous thrombosis and monitoring clot

resolution on streptokinase therapy. Blood, Suppl 62:310,1983.

28. Siegel RS, **Clarke-Pearson DL**, Coleman RE: Indium-111-labeled platelets in the detection of deep venous thrombosis and pulmonary embolism. Blood 50:223, 1982.

29. Postoperative thromboembolism prophylaxis in gynecologic oncology: A prospective, controlled trial of low-dose heparin and external pneumatic calf compression. Gynecol Oncol, 1982.

Un-refereed Publications

1. **Clarke-Pearson DL**. Prevention and Management of Venous Thromboembolism (15 minute Video) for the Globathon to End Women's Cancer. September 2014.

2. **Clarke-Pearson DL**, Brincat C, Tang J. Prevention and Management of Venous Thromboembolism in Gynecologic Surgery. ACOG Update. Vol 37, No 2. August, 2011.

3. **Clarke-Pearson DL**. Preventing Venous Thromboembolism: Evidence-based Perioperative tactics. OBG Management. 2006, 18: 56-66.

4. **Clarke-Pearson DL**: Prevention of venous thrombosis following gynecologic surgery in menopausal patients. Menopausal Medicine Vol 4 (4):6-9, 1996.

5. Rodriguez GC, **Clarke-Pearson DL**: What is the appropriate preoperative and prenatal screen for hemostatic disorders? Obstet Gynecol Forum, November 1991.

6. **Clarke-Pearson DL**, Hume RF: Venous thromboembolic disease in obstetrics and gynecology: Prevention, diagnosis and treatment. Curr Problems in Obstet Gynecol, 1989.

7. Hunter VJ, Christensen C, **Clarke-Pearson DL**: Evaluation and management of the abnormal Papanicolaou smear. North Carolina Family Physician, 1989.

8. **Clarke-Pearson DL**, Krumholz AB: When the pap smear is equivocal. Patient Care 23:43-47, 1989.

9. **Clarke-Pearson D**, DiSaia P, Mastroianni L, Richart R, Weingold AB: Advances in managing endometrial carcinoma. Patient Care 22:102-116, 1988.

10. Creasman WT, Smith EB, **Clarke-Pearson DL**: Current concepts of gestational trophoblastic disease. Female Patient, 1984.

11. Creasman WT, **Clarke-Pearson DL**: Abnormal cervical cytology: Spotting it, treating it. Contemporary Obstet Gynecol 21:53-76, 1983.

12. Hammond CB, **Clarke-Pearson DL**, Soper JT: Management of patients with gestational trophoblastic neoplasia: Experience of the Southeastern Regional Center. In: The Proceedings of the World Congress on Gestational Trophoblastic Neoplasia, Nigeria, 1982.

13. **Clarke-Pearson DL**: Application of impedance phlebography in obstetrics. Symposium on Noninvasive Diagnostic Techniques in Vascular Disease. San Diego, California, 1979.

14. **Clarke-Pearson DL**: The O.S.R. as an influence to health education. The Scalpel, Journal of Alpha Delta Alpha Medical Honor Society, 1975.

Teaching Record

2022 Society of Pelvic Surgeons Annual Meeting: Panel Moderator- "Where are the limits to cancer excision and reconstruction?"

2020 George Washington University Medical Oncology Board Review Course (Faculty) "Cervix, vulva vagina cancer and gestational trophobalastic disease" (by zoom)

2019 Presidential Speaker, South Atlantic Association of ObGyn Annual meeting,
Sea Island Georgia

George Washington University Medical Oncology Board Review Course (Faculty) "Cervix, vulva vagina cancer and gestational trophobalastic disease"

2018 Visiting Professor, University of West Virginia, Morganton, WVa
Antonio Palladino Lectureship

George Washington University Medical Oncology Board Review Course (Faculty) "Cervix, vulva vagina cancer and gestational trophobalastic disease"

2016 Plenary Session, Society of Pelvic Surgeons, St Louis, Mo. "Venous Thromboembolism:

Minimally Invasive Compared with Open Hysterectomy for Endometrial Cancer"
Key Note Speaker. ACOG Armed Forces District Meeting, Orlando, FL

Visiting Professor and Research Day Judge, Cleveland Clinic Department of Obstetrics and Gynecology and Women's Research Institute, Cleveland, Ohio

Visiting Professor, Department of Obstetrics and Gynecology, Carilion Roanoke Memorial Hospital, Roanoke, Va.

George Washington University
Medical Oncology Board Review Course (Faculty) "Cervix, vulva vagina cancer and gestational trophobalastic disease"

2015 Visiting Professor
University of Michigan

George Washington University
Medical Oncology Board Review Course (Faculty)

2014 Visiting Professor
Massachusetts General Hospital, ObGyn Department Grand Rounds Boston, MA
Invited speaker: ACOG District II Annual Meeting, New York City "Uterine Morcellation: A Decision Analysis"

George Washington University Medical Oncology Board Review Course (Faculty) "Cervix, vulva vagina cancer and gestational trophobalastic disease"

2013 Visiting Professor and Resident Research Day Judge
Department of Obstetrics and Gynecology, University of Nebraska Omaha, NE
Visiting Professor, Emory University Department of Obstetrics and Gynecology Atlanta, GA

Key Note Speaker: Inaugural Ireland Ovarian Cancer Forum "Surgery for Ovarian Cancer"
Dublin, Ireland

Panel Moderator, American College of Surgeons Annual Clinical Congress "General Surgery in the Pregnant Patient" Washington, DC

George Washington University
Medical Oncology Board Review Course (Faculty)

2012 Clifford Wheless Lectureship, Johns Hopkins University, Department of Obstetrics and Gynecology, Baltimore, MD

Panel Moderator, American College of Surgeons Annual Clinical Congress "Multidiciplinary approach

to Vaginal Fistula" Chicago, IL

Resident Research Day Judge and Visiting Professor
Department of Obstetrics and Gynecology, Greenville Hospital System, Greenville, SC

Visiting Professor: University Teaching Hospital, Department of Obstetrics and Gynecology, Lusaka, Zambia

Cervical Cancer management
Current Treatment of Vulvar Carcinoma

Visiting Professor: Center for Infectious Disease Research in Zambia (CIDRZ), Lusaka, Zambia

Human Papilloma Vaccine for the Prevention of Cervical Cancer

Visiting Professor: Inova Fairfax Hospital Women's Center, Fairfax VA

Visiting Professor: Emory University School of Medicine, Department of Obstetrics and Gynecology. Atlanta, GA

George Washington University
Medical Oncology Board Review Course (Faculty)

2011 Sloane Symposium: Current Issues and Controversies in Obstetrics and Gynecology Columbia University, College of Physicians and Surgeons, Department of Obstetrics and Gynecology
Vandewiele Lecturer: "Prevention of Venous Thromboembolism in Gynecologic Surgery"
Guest Lecturer and Judge: Resident Research Day, Columbia University "What to say in your Operative Note"

University of Kentucky: Residents' Research Day Speaker
Virginia Commonwealth University School of Medicine. Department of Obstetrics and Gynecology
Annual Ware-Dunn Symposium Keynote speaker

George Washington University
Medical Oncology Board Review Course (Faculty)

2010 New England Obstetrical and Gynecological Society, Sturbridge, MA
Invited Speaker

ACOG Annual Clinical Meeting, San Francisco, CA
Luncheon Seminar Leader

George Washington University Medical Oncology Review Course
Washington, DC
Invited Faculty

MD Anderson Cancer Center Medical Oncology Review Course
Houston, TX
Invited Faculty

The Society of Gynecologic Oncology of Canada
Royal College of Physicians and Surgeons of Canada
Annual Meeting
Invited Lecturer: Thromboprophylaxis in Minimially Invasive Surgery

Visiting Professor
University of South Florida, Tampa, FL
2009 Resident Research Day

ACOG District IV Meeting, Asheville, NC
"Prevention of Venous Thromboembolism"
"Stump the Professors: Panel"

American College of Surgeons' Annual Meeting, Chicago, IL
"Complicated Hysterectomy"

Visiting Professor: Hartford Hospital, Hartford CT

Visiting Professor: University of Connecticut, Farmington, CT

Visiting Professor: Memorial Sloan Kettering Cancer Center

Southern Obstetric and Gynecologic Seminar, Asheville, NC
"Prevention of VTE following Gynecologic Surgery"
"The Operative Note: What to say?"

Woman's Hospital 7th Annual Founders Commerative Lectureship, Woman's Hospital, Baton Rouge, LA

2008 Visiting Professor, Department of Obstetrics and Gynecology, Yale University

Course Director, ACOG CME Course "Complex Pelvic Surgery", Phoenix, AZ

Invited Speaker: First Annual Gynecologic Cancer Symposium, Washington, DC April 18, 2008

Visiting Professor, University of Wisconsin Resident's Research Day, Ben M. Peckman Memorial Lecturer, Madison, WI

ACOG representative to Symposium on Surveillance for Venous Thrombosis, American Society of Hematology, Washington DC

2007 Visiting Professor, Department of Obstetrics and Gynecology, University of Miami

Faculty, University of Utah CME Course "Obstetrics and Gynecology: Update and Current Controversies" Park City Utah

Visiting Professor, Department of Obstetrics and Gynecology St. Louis University, St. Louis MO

Invited Lecturer: Marvin Camel Memorial Lecture, Washington University, Department of Obstetrics and Gynecology, St Louis, MO

Presidential Panel Speaker: Society of Pelvic Surgeons Annual Meeting, Cleveland, OH "What Can We do to prevent Venous Thromboembolism?"

2006 Course Director: ACOG Annual Clinical Meeting: "Complex Gynecologic Surgery, Washington DC

Invited Speaker, ACOG District IV Annual Meeting, Palm Beach, FL

2005 Course Director: ACOG Annual Clinical Meeting: "Complex Gynecologic Surgery, San Francisco

Course Director: ACOG Free-standing CME Course "Complex Gynecologic Surgery, Preventing Complications" Dana Point, CA

2004 Society of Surgical Oncology: Symposium on Prevention of Venous Thromboembolism in the Surgical Oncology Patient

Postgraduate Course Faculty: ACOG Cancun, Mexico "Advanced Gynecologic Surgery"

American College of Obstetricians and Gynecologists, Annual Clinical Meeting, Philadelphia, PA
Faculty, 120 Course: Special Topics for the Advanced Gynecologic Surgeon
Faculty, Luncheon Seminar: "Prevention of Postoperative Venous Thromboembolism"
Speaker: "Late-breaking News in Gynecologic Oncology"

Visiting Professor, University of Kansas School of Medicine, Truman Medical Center

Faculty: ACOG Indiana Section Meeting, Indianapolis
"Surgery in the Obese Patient", "Surgical Instruments"

2003 Faculty, The 3rd Annual Cancer Conference, Aultman Cancer Center, Canton Ohio "Prevention and Management of Perioperative Venous Thromboembolism in the Gynecologic Cancer Patient"

Visiting Professor, Department of Obstetrics and Gynecology, University of Massachusetts, Worcester, MA

2002 Visiting Professor
Bowman Gray School of Medicine

Residents' Day Research Judge
Winston Salem, NC

American College of Surgeons' Annual Clinical Congress
Panel Discussant: "Surgical Problems: Unexpected adenxal mass, tuboovarian abscess"
Video Presentation: "Intraoperative Radiation Therapy for the treatment of Recurrent Cervical Carcinoma"
Discussant: Video Presentation "Laparoscopic Infrarenal paraarotic lymphadenectomy"

2001 ACOG Annual Meeting
Postgraduate Seminar
Gynecologic Surgery in the Elderly

George Washington University
Medical Oncology Board Review Course (Faculty)

2000 Keynote Speaker
Knoxville Obstetrical and Gynecological Society

ACOG Annual Meeting (Course Director)
Postgraduate Course
Gynecologic Surgery for the Advanced Pelvic Surgeon

Visiting Professor
East Carolina University School of Medicine

Visiting Professor
Pennsylvania State University School of Medicine (Hershey)

George Washington University
Medical Oncology Board Review Course (Faculty)

1999 ACOG Annual Meeting (Course Director)
Postgraduate Course
Gynecologic Surgery for the Advanced Pelvic Surgeon

George Washington University School of Medicine
Medical Oncology Board Review Course (Faculty)

Visiting Professor
University of Virginia Health Sciences Center

ACOG Annual Meeting (Course Director)
Postgraduate Course
Gynecologic Surgery for the Advanced Pelvic Surgeon

1998 ACOG Annual Meeting (Course Director)
Postgraduate Course
Gynecologic Surgery for the Advanced Pelvic Surgeon

George Washington University School of Medicine
Medical Oncology Board Review Course (Faculty)

Visiting Professor
Temple University School of Medicine

Keynote Speaker
Maryland Obstetrical and Gynecological Society

Visiting Professor
University of Louisville
"Prevention of Postoperative Venous Thromboembolism"
"Management of Patients with Thrombophilias"

1997 Visiting Professor
University of Utah, Salt Lake City

ACOG Annual Meeting (Course Director)
Postgraduate Course
Advanced Surgery for the Gynecologist

Visiting Professor
Cleveland Clinic Foundation
Department of Obstetrics and Gynecology
Cleveland, Ohio

George Washington University School of Medicine
Medical Oncology Board Review Course (Faculty)

Keynote Speaker
Chicago Gynecological Society

Visiting Professor
University of Louisville School of Medicine

Visiting Professor
Washington University School of Medicine

Visiting Professor
Johns Hopkins University School of Medicine

ACOG Annual Clinical Meeting
Faculty, 120 Course: Special Topics for the Advanced Gynecologic Surgeon
Faculty, Seminar: "Gynecologic Surgery in the Elderly"
Faculty, Luncheon Seminar: "Prevention of Postoperative Venous Thromboembolism"

American College of Surgeons' Annual Clinical Congress
Panel Discussant: "Management of Gynecologic Problems Encountered by the General Surgeon at the time of Surgery. "Surgical Management of Ovarian Cancer Discovered at the time of Laparotomy"

1996 Visiting Professor
Dartmouth Medical School

Director ACOG Postgraduate Course
Annual Clinical Meeting

Special Problems for the Advanced Gynecologic Surgeon

Visiting Professor
University of Tennessee School of Medicine
Chattanooga, Tennessee

Visiting Professor
University of South Florida School of Medicine
Tampa, Florida

Visiting Professor
Washington University School of Medicine
St. Louis, Missouri

John L. McKelvey Lecturer
New Treatments for Ovarian Cancer
University of Minnesota
Minneapolis, Minnesota

Faculty - Taubman Ovarian Cancer Symposium
St. Joseph's Hospital
Tulsa, Oklahoma

ACOG Postgraduate Course (Course Director)
San Juan, Puerto Rico
Advanced Pelvic Surgery

1994 ACOG Clinical Meeting CME Course
Orlando, FL
"Gynecologic Cancer"

Guest Speaker
Seattle Gynecological Society Assembly

1993 Visiting Professor - Department of OB/GYN
University of Massachusetts
Worcester, Massachusetts

ACOG Clinical Meeting - CME Course
Washington, DC
"Gynecologic Surgery"

PostGraduate Course in Obstetrics and Gynecology
Kaiser-Permanente - Maui, Hawaii
"Screening for Ovarian Cancer"
"Management of CIN with LEEP"
"Difficult Vaginal Hysterectomy"
"Incisions and Wound Closures"

Duke/US Surgical Course
"Laparoscopic Assisted Difficult Hysterectomy"

Visiting Professor - Mt. Sinai Hospital
Baltimore, MD
"Prevention of Thromboembolism"
"Management of Ovarian Cancer"

1992 Visiting Professor - Department of OB/GYN
University of Massachusetts
Worcester, Massachusetts

1991 Visiting Professor
George Washington University School of Medicine

Course Director - ACOG Course (120 series)
Annual Clinical Meeting
New Orleans, Louisiana
"Gynecologic Oncology for the Practicing Gynecologist"

Course Director - ACOG Course
Vancouver, British Columbia, Canada
"Gynecologic Surgery"

Visiting Professor
Florida Hospital Cancer Center
Orlando, Florida

Paper Presentation
Poster Presentation
Society of Gynecologic Oncologists
Orlando, Florida

Visiting Professor
Ohio State University School of Medicine
Columbus, Ohio

Medical Oncology Board Review Course
George Washington University
Washington, DC
"Cervical, Vulvar and Vaginal Cancer"
"Gestational Trophoblastic Disease"

1990 Society of Gynecologic Oncologists
Breakfast Seminar
"Diagnosis and Prevention of Postoperative Venous Thrombosis"

Course Director - ACOG Course (120 Series)
Annual Clinical Meeting
San Francisco, California
"Update in Clinical Gynecologic Oncology"

Seminar, ACOG Clinical Meeting
"Prevention of Postoperative Venous Thrombosis"

1989 Tumor Conference, Moore Regional Hospital
Pinehurst, North Carolina

Course Director - ACOG Course (120 Series) Annual Clinical Meeting, Atlanta, Georgia
"Update in Clinical Gynecologic Oncology"

Seminar, ACOG Clinical Meeting
"Management of Early Ovarian Cancer"

Luncheon Conference, ACOG Annual Meeting
"Reproductive Outcome Following Cancer Treatment"

Medical Oncology Board Review Course, George Washington University, Washington, DC
"Cervical Cancer"

1988 Matt Weiss Symposium
St. Louis, Missouri

ACOG Annual Clinical Meeting
Poster Session Presentation
Review of Clinical Research Paper
Review of Surgical Film
Clinical Seminar Presentation

ACOG Course
Juneau, Alaska
"Gynecologic Surgery"

1987 Update in Obstetrics and Gynecology
Williamsburg, Virginia

North Carolina Obstetrical and Gynecological
Society Meeting, Southern Pines, North Carolina

Visiting Professor, University of Minnesota School of Medicine, Minneapolis, Minnesota

ACOG Annual Clinical Meeting
Clinical Paper Presentation
Clinical Seminar Presentation

Southern Obstetrics and Gynecology Seminar
Asheville, North Carolina

Satellite Teleconference
Chicago, Illinois
"Selected aspects of the care of the menopausal woman"

Chicago Medical Schools' Review Course
Chicago, Illinois
"Endometrial Carcinoma"

Grants

Active Grants:					
None at this time					
Completed Grants:					

Project Period	Agency	Title	Amount	Role	% of Effort
9/27/05-3/10/10	NIH/NICHD	Women's Reproductive Health Research (WRHR) Career Development Center at UNC - HDD050113-02	$370,367 Annual Direct Costs	Principal Investigator	
3/1/00-3/31/02	Pharmacia Upjohn Pharmaceuticals	Randomized Comparison of Low Molecular Weight Heparin vs. Oral Anticoagulant Therapy for Long Term Anticoagulation in cancer patients – 98-Frag-069	$ 73,000	Principal Investigator	
1/1/99-6/15/00	Zeneca Pharmaceuticals , Inc	Phase II/III Trial of IV ZD9331 in patients with recurrent refractory ovarian cancer	$ 18,320	Principal Investigator	
6/1/98-6/1/00	Pharmacia Upjohn Pharmaceuticals	Prospective Randomized Trial Comparing Pneumatic Compression stockings To Low Molecular Weight Heparin (dalteparin) in the prevention of postoperativevenous Thrombosis	$ 100,760	Principal Investigator	
06/01/95 - 05/31/2000	National Cancer Institute	Hyperthermia and Perfusion Effects in Cancer Therapy	$10,930,969	Investigator	2%
03/15/98-03/14/00	Novartis Pharmaceuticals	PSC 833 with taxol and carboplatin vs. carboplatin alone in patients with stage III ovarian cancer	$ 102,240	Principal Investigator	
8/1/97-7/31/99	NIH	Hyperthermia and Perfusion Effects in Cancer Therapy	$ 1,832,501	Co-Investigator	
5/28/97-12/31/98	Smithkline Beecham Pharmaceuticals	Oral Topotecan Single Agent for 5 days in patients with ovarian cancer	$ 81, 600	Principal Investigator	
01/01/93-12/31/98	National Cancer Institute	Comprehensive Cancer Center Core Support Grant	$ 4,442,597	Program Director	10%
06/01/94 -	National Cancer	Autologous Bone	$641,613	Investigator	10%

03/31/97	Institute	Marrow Transplantation in Breast and Ovarian Cancer: Project IB			
03/15/96-05/30/96	Ethicon, Inc	An Open, Controlled, Rand, Multicenter, Evaluation of Dyed Monocryl (Poliglecaprone 25) Synthetic Absorbable Suture as Compared to Surgical Gut (Chromic) Absorbable Suture	$ 4,000	Principal Investigator	
1987-1996	American Cancer Society	Clinical Oncology Fellowship	$ 20,000 (Direct)	Principal Investigator	5%
10/01/92-09/30/94	Centocor, Inc.	CA125 Post-Market Evaluation	$ 8,750	Principal Investigator	5%
12/15/93-09/21/94	Smith-Kline Beecham Pharmaceutical	Phase III Topotecan versus Taxol in Women with Advanced Ovarian Carcinoma	$ 37,500	Principal Investigator	5%
12/15/93-08/14/94	Smith-Kline Beecham Pharmaceutical	II Topotecan, Given as Five Daily Doses Every 21 Days in Ovarian Cancer	$ 37,500	Principal Investigator	10%
07/01/89 - 03/31/94	Gynecologic Oncology Group	Gynecologic Oncology Group, Duke University Medical Center	$ Contingent on number of patients	Co-Principal Investigator	30%
01/01/91 – 09/01/93	Organon, Inc.	ORG 2766 as a Neuroprotector from Cisplatin Chemotherapy for Ovarian Cancer	$97, 575	Principal Investigator	10%
02/01/91 - 01/31/92	Organon, Inc.	Decapeptyl Treatment of Advanced Ovarian Cancer (Phase II Trial)	$100,098	Principal Investigator	10%
11/01/90-10/31/91	Cytogen, Inc.	111In-CYT-103 Oncoprobe Evaluation of Ovarian Cancer	$ 124,000	Principal Investigator	10%
07/01/86-06/30/91	National Institutes of Health	Avoidable Mortality from Cancers in Black Populations	$ 4,647,291	Co-Investigator	10%
06/01/87 - 05/31/89	Public Health Service	Improved Instrumentation for the Diagnosis of Venous Thrombosis	$162,804 (Direct)	Co-Principal Investigator	10%
05/01/88 -	National Cancer	Gynecologic	$97,073	Co-Principal	10%

04/30/89	Institute	Oncology Group, Duke University Medical Center	(Direct)	Investigator	
01/01/88 - 12/30/88	Centocor, Inc.	Evaluation of the Safety and Preliminary Diagnostic Accuracy of IV Administered Indium-111-labeled OC-125 Monoclonal Antibody in Patients with Carcinoma of the Ovary	$ 20,000 (Direct)	Co-Principal Investigator	5%
01/01/88 - 12/30/88	Centocor, Inc.	Evaluation of the Safety and Preliminary Diagnostic Accuracy of IV Administered Indium-111-labeled OV-TL3 Monoclonal Antibody in Patients with Carcinoma of the Ovary	$ 40,000 (Direct)	Co-Principal Investigator	5%
05/01/85- 04/30/87	National Cancer Insitute	Illinois Cancer Council - Gynecologic Oncology Group	$ 21,000 (Direct)	Co-Principal Investigator	10%
07/01/81- 06/30/84	American Cancer Society	Junior Faculty Clinical Fellowship	$ 35,000	Principal Investigator	30%
01/01/83- 12/31/83	Trent Foundation	In-vitro chemotherapy sensitivity testing of ovarian carcinoma	$ 1,000	Principal Investigator	5%

PROFESSIONAL SERVICE

To discipline:

A. National/International

2023 President Elect, Society of Pelvic Surgeons

2021- 2022 Chair, NRG Oncology Data Monitoring Committee (Gynecologic Oncology Group)

2019-2023 Vice President, Society of Pelvic Surgeons
Editorial board member: Journal of Gynecologic Surgery

2018-2020 Chair, Council of University Chairs of Obstetrics and Gynecology

2014 Chair, External Site Visit Committee, Department of Obstetrics and Gynecology, Penn State
2014 University College of Medicine, Department of Obstetrics and Gynecology Member,
2014 CUCOG Executive Board

2011 Member, American College of Surgeons Advisory Committee (ObGyn)
2011 Member, CUCOG Executive Committee
2011 Chair, ACOG Committee on Gynecologic Practice
2011 Chair, SGO Nominating Committee

2010-2013 Immediate Past President, SGO
2010-2013 Member, ACOG Executive Board (Representing the Society of Gynecologic Oncology)
2011-2013 Chair, Committee on Gynecologic Practice, ACOG
2007 -2010 Member, Education/Research Committee, Society of Pelvic Surgeons
1988- 2005 Board Examiner: Obstetrics and Gynecology , ABOG
2010-2011 Vice-Chair, Committee on Gynecologic Practice, ACOG
2010 President, Society of Gynecologic Oncologists
2009-2010 Editorial Board, Precis, Gynecology, ACOG
Program Chair, Society of Pelvic Surgeons

2008
2008-2010 Committee on Gynecologic Practice, ACOG
2008 President Elect II, Society of Gynecologic Oncologists
2008 Chair, Membership Committee. Society of Pelvic Surgeons
2007-2008 Vice President, Society of Gynecologic Oncologists

2007
2007 Editorial Board: Precis, Oncology, ACOG
2007 SGO Executive Council, Society of Gynecologic Oncologists
2007 Chair, Task Force to select Editor and Chief, *Gynecologic Oncology*, Society of Gynecologic Oncologists
2007 Co-Chair, Strategic Planning Committee, Society of Gynecologic Oncologists
2007 Member, By-laws Committee, Society of Gynecologic Oncologists

2005
2005 NC Breast and Cervical Cancer Control Program's (BCCCP) Medical Advisory Committee, North Carolina Department of Environment, Health, and Natural Resources
2005-2019 Member, Clinical Cancer Committee, Moses Cone Health System
2005-2019 Director, Gynecologic Oncology Program, Moses Cone Health System
2005-2019 Member, Cancer Center Executive Committee, Moses Cone Health System
1998-2005 Member, Executive Committee Cancer Center Clinical Service Unit, Duke University
1998-2005 Co-Medical Director, Surgical Oncology Clinic, Duke University
1992-2005 Member, Operating Room Committee, Duke University
1991-2005 Principal Investigator, Duke University, Gynecologic Oncology Group
1987-2005 Director of Gynecologic Oncology Fellowship Program (Duke Univ), ABOG
1987-2005 Director, Gynecologic Oncology Program, Duke Comprehensive Cancer Center, Duke University
1987-2005 Member, Steering Committee Strategic Planning Task Force, Duke Comprehensive Cancer Center, Duke University
1987-2005 Member, Executive Committee, Duke Comprehensive Cancer Center, Duke University

2003
2003 Nominating Committee, Society of Gynecologic Oncologists
2003 President and Program Chairman, Mid Atlantic Gynecologic Oncology Society

2002

2002 President-Elect, Mid Atlantic Gynecologic Oncology Society
2002 Member, Membership Committee, Society of Pelvic Surgeons
2002 Member, Oncology Strategic Planning Council, Duke University

2001

2001 Editorial Board: Precis, Oncology, ACOG
2001 Board Examiner: Gynecologic Oncology, ABOG

2000

2000 Member, Nominating Committee (AGOS Foundation)
2000 Program Chairman (Annual Meeting), Mid Atlantic Gynecologic Oncology Society
1994-2000 Member, Education Committee, Society of Gynecologic Oncologists

1999

1996-1999 Member, Fellowship Committee, AGOS

1998

1994-1998 Council Member, Society of Gynecologic Oncologists
1990-1998 Ovarian Cancer Committee, Gynecologic Oncology Group

1997

1993-1997 Editorial Board Member, Duke Cancer Report, Duke University
1993-1997 Committee on Gynecologic Practice, ACOG
1993-1997 Chairman, Committee on Gynecologic Oncology Practice, ACOG
1993-1997 ACOG Liaison Representative to the Society of Gynecologic Oncologists
1994-1997 Member, Committee on Clinical Practice, Society of Gynecologic Oncologists

1995

1994-1995 Chairman, 1995 Program Committee, Society of Gynecologic Oncologists

1994

1993-1994 Ad hoc Council Member, Society of Gynecologic Oncologists
1993-1994 Ad hoc Committee on Clinical Practice Policy Development Society of Gynecologic Oncologists
1994 Society of Pelvic Surgeons

1993

1991-1993 Chairman, Gynecology Committee, North Carolina OB/GYN Society
1991-1993 Member, Professional Activities Committee, North Carolina OB/GYN Society
1993 Medical Director, Duke North Hospital, 5900 Unit, Duke University
1993 Fellow, American Gynecological and Obstetrical Society
1993 Member, Ad hoc Committee to Define Criteria for Tenure in Clinical Medicine , Duke University
1993 Department of Surgery Chairman Search Committee, Duke University

1992

1990-1992 Member, Task Force on Cervical Cancer, Chairman, Subcommittee on Impact of Appropriate Follow-up Care, North Carolina Department of Environment, Health, and Natural Resources

1991

1987-1991 Co-Principal Investigator, Duke University Grant, Gynecologic Oncology Group
1987-1991 Committee on Technical Bulletins, ACOG
1991 Board Examiner: Gynecologic Oncology, ABOG
1991 Member, Director of Surgical Pathology Search Committee, Duke University

1990

1990 Member, Department of Pathology Chairman Search Committee, Duke University
1982-1990 Gynecologic Management Committee, Gynecologic Oncology Group

1989

1989 Fellow, American College of Surgeons

1988

1988 Mid-Atlantic Gynecologic Oncology Society
1988 Southern Obstetrical and Gynecological Seminar
1988 International Gynecologic Cancer Society
1988 Mid-Atlantic Gynecologic Oncology Society
1988 Southern Obstetrical and Gynecological Seminar

1987

1985-1987 Chicago Medical Society
1985-1987 Illinois Cancer Council
1985-1987 Illinois State Medical Society
1985-1987 Chicago Association of Gynecologic Oncologists
1987 North Carolina Medical Society
1987 North Carolina Obstetrical and Gynecological Society
1987 American Society of Clinical Oncologists

1986

1986 Chicago Gynecological Society

1985

1982-1985 Co-Principal Investigator, Duke University Grant, Gynecologic Oncology Group
1985 Central Association of Obstetricians and Gynecologists
1985 Central Association of Obstetricians and Gynecologists
1985 American Medical Association

1982

1982 Gynecologic Oncology Group
1982 Society of Gynecologic Oncologists
1982 Fellow, American College of Obstetricians and Gynecologists

1979

1979 Piedmont Obstetrical and Gynecological Society
1979 Bayard Carter Society of Obstetricians and Gynecologists
1979 Junior Fellow Section Chairman, ACOG

1978

1978 Junior Fellow Section Co-Chairman, ACOG

1977

1977 Junior Fellow Section Program Chairman, ACOG

B. Within UNC-Chapel Hill

2018-2021 Member, School of Medicine Promotions and Tenure Committee
2013-2019 Member, UNC Hospitals Committee of Perioperative Leaders
2011-2019 Member, Physicians and Associates Executive Committee
Member, P&A Finance and Compensation Committee
Member, P&A Committee on Payer Relations

2009- Member, Strategic Planning Committee: Hillsboro Hospital
2009-2019 Member, Strategic Planning Committee UNC HCS
2008-2019 Member, Dean's Advisory Committee on Part-Time Tenure Track Positions 2008-present Member Geographic Strategic Planning Committee
2008- 2019 Member UNC Strategic Planning Committee: Outpatient Surgery 2008-present Member UNC Strategic Planning Committee: Oncology
2007-2019 Member, Sheps Center Advisory Board
2007-2019 Member, Center for Women's Health Research Advisory Board
2007-2009 Team Leader (Attending Physicians' Experience) UNC Hospital Commitment to Caring 2006-present Medical Director, NC Women's Hospital Ambulatory Services
2005-2019 Dean's Advisory Committee
2005-2019 UNC Hospital Executive Committee
2005-2019 Physician and Chief, North Carolina Women's Hospital
2005-2019 Member, Physician and Associates Board/Faculty Physicians
2005-present Member, UNC Lineberger Cancer Center
2006, 2007 Chair, Data Safety Monitoring Board: An International Multi-Center Phase III Study of Chemoradiotherapy versus chemoratiotherapy plusvhyperthermia for locally advanced cervical

Editorial Board Member

1994-2004 Postgraduate Obstetrics and Gynecology
2003 Précis, Oncology, Second Edition
1995-2001 Associate Editor, Journal of Gynecologic Techniques
1994-2000 Gynecologic Oncology
2012-2015 Obstetrics and Gynecology
2020-present Journal of Gynecologic Surgery

Journal Reviewer

Obstetrics and Gynecology

New England Journal of Medicine

American Journal of Obstetrics and Gynecology Journal of the American Medical Association (JAMA)

Annals of Internal Medicine

Pharmacotherapy

Fertility and Sterility

Gynecologic Oncology Cancer

International Journal of Gynecology and Obstetrics Journal of Pelvic Surgery

Journal of Gynecologic Surgery

Exhibit B

Daniel Clarke-Pearson, M.D.
Materials Considered

1. "A Survey of the Long-Term Effects of Talc and Kaolin Pleurodesis." *British Journal of Diseases of the Chest* 73 (1979): 285–88.
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Other Materials

3rd Supplemental MDL Report of William Longo, PhD – Analysis of Non-Historical J&J's Talcum Powder Consumer Product Containers and J&J Chinese Historical Talc Retain Samples, dated November 17, 2023.

William E. Longo, PhD – MDL Johnson's Baby Powder Application and Exposure Container Calculations for Six Ovarian Cancer Victims Bellwether Cases, dated November 17, 2023.

Amended Expert Report of Shawn Levy, PhD, dated November 15, 2023.

Exhibit C

Daniel Clarke-Pearson, MD
Medical Legal Testimony in last 5 years

Date: January 7, 2019
Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

March 27, 2020
Khan v. Karl Storz, Howard Jones, Noh Goodman, Valley Health System
SUPERIOR COURT OF NEW JERSEY
2 LAW DIVISION - ESSEX COUNTY

March 9, 2021
Case: Ruscitto v. Jones

Date: September 13, 2021 and September 14, 2021
Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

Date: January 17, 2024 and March 8, 2024
Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

Hourly Rate: $900/hour